NOV - 7 2000 K00433

SECTION 2 - 510(K) SUMMARY

Name and Address of Applicant
Nihon Kohden America, Inc.
Attn: Regulatory Affairs
2601 Campus Drive
Irvine, California 92612-1601
Phone: (949) 250-3959
Fax: (949) 250-3210

The device has been classified as Class III by the Cardiovascular Device Classification Panel under 21 CFR Part 870.1025 "Monitor, Physiological, Patient (with arrhythmia detection or alarms)" per MHX.

Common names for the device include Central Nurse Station, Central Monitoring Station and Telemetry Monitoring Station.

The predicate marketed device is the Nihon Kohden CNS-8311A and CNS-8351A Central Station per 510(k) # K935877, commercial distribution certification dated May 24, 1995.

The device is intended for use by medical professionals to provide cardiac and vital signs monitoring for multiple patients within a medical facility. The device will display and record physiological data from individual bedside monitors and telemetry receiver/transmitters and generate an alarm when a measured parameter falls outside a preset limit or when an arrhythmia is detected. Arrhythmia detection and alarm determination are functions of the individual bedside or telemetry channel.

To date, no special controls or performance standards are known or established for this device.

The device is not sterile.

The device is not contacting. Therefore, no good laboratory practice studies were required per 21 CFR 58.

The device was subjected to electromagnetic, environmental, safety and performance testing procedures. These tests verified the operation of the device. Software validation tested the operation of the software functions of acquiring, displaying and recording of all functions of the device. The results confirmed that the device performed within specifications.

Therefore based on the above, Nihon Kohden believes that the CNS-9301, CNS-9302 and CNS-9303 Central Stations are substantially equivalent to the Nihon Kohden CNS-8311A and CNS-8351A Central Station.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 7 2000

Bonnie Bishop
Regulatory Affairs Manager
Nihon Kohden America, Inc.
90 Icon Street
Foothill Ranch, CA 92610

Re: K001433
Nihon Kohden CNS-9300 Series Central Station
Regulatory Class: III (three)
Product Code: MHX
Dated: August 25, 2000
Received: August 28, 2000

Dear Ms. Bishop:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act

response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4346. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices
and Radiological Health

Enclosure

G. Indications for Use Statement

510(k) Number (if known): K001433

Device Name: CNS-9301, CNS-9302 and CNS-9303 Central Stations

Indications for Use:

The CNS-9300 Series Central Station is intended for cardiac and vital signs monitoring for multiple patients. The device will display and record physiological data from individual bedside monitors and telemetry receiver/transmitters and generate an alarm when a measured parameter falls outside a preset limit or when an arrhythmia is detected.

This product will be available for use by medical personnel on all patient populations within a medical facility.

Division of Cardiovascular & Respiratory Devices
510(k) Number K001433